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MEXICAN POLICY FOR TRANSPORT OF GMO AND BIOTECHNOLOGICAL PRODUCTS

SHIPPING POLICY HACKATHON

OVERVIEW

Although there are several regulations to which an iGEM project may be subject, some of them have a more significant impact on the transport of biological material, including DNA and genetically modified organisms (GMOs). An overview of this document can be found in the following paragraphs.

SCOPE

The present policy overview will focus on legislation applicable to Mexican cases, which involve regulating both types of transport: within the national territory and across borders, either importations or exportations. In particular, the present legal pieces consist of the Law on Biosecurity of Genetically Modified Organisms (LBOGM, for its acronym in Spanish), a law that oversees compliance on transporting, commercializing, and studying GMOs. At the same time, the other regulation encompasses the identification and classification of the most commonly transported hazardous substances and materials, according to their class, risk division, secondary risk, the number assigned by the United Nations, the special provisions to which their transport must be subject, quantitative limits excepted quantities allowed, and the corresponding packaging and packaging instructions, and methods.

These two regulations were selected due to their relationship with some of the most seen biological products related to synthetic biology: DNA and genetically modified organisms. These are related to the development and eventual commercialization of an iGEM project.

IMPACT OF POLICIES ON SYNTHETIC BIOLOGY

Policies have a significant impact on the development of synthetic biology in Mexico, as the science development can be slowed down, which usually happens due to redundancies or gray areas on the country's current laws. In addition to this, as most policies in Mexico related to biotechnology focus only on plants, there is a problem with the regulation of other products made with synthetic biology, for example, pharmaceutics, biomaterials, and products that are released into the environment. These policies directly impact the development of science in our

country; that's why we must focus on analyzing what is wrong, try to improve it, and improve the biotechnological development of our country.

METHODS OF RESEARCH

To understand the corresponding legal documents, several sources were consulted. In the first place, the LBOGM was accessed and consulted, as well as the NOM-002-SCT-2011, which was accessed through the CONACYT web page, where all of the current regulations of biosafety in Mexico are available. Following these, additional information on these laws was googled and thoroughly selected in order to better comprehend these laws. After analyzing these two laws, the strengths and weaknesses were compared to similar laws in the US, more specifically the USDA's approach towards the same area, to offer a more in-depth contrast between the Mexican policies and regulations; and the more liberal American regulations regarding the transport of biological material and other biotechnology-related products.

TABLE OF POLICIES

Policy Name	Country/ Region	Biological materials	Kinds of shipping	Limits	Relevant policy bodies	Other Notes	Link to details of policy
Law on Biosecurity of Genetically Modified Organisms (LBOGM, for its acronym in Spanish)	Mexico	Genetically Modified Organisms	Transportation within the national territory International importation and exportation	Bias towards genetically modified crops to be commercialized. Limited description of the requirements for the transport of GMOs.	Secretariat of Finance and Public Credit (SCHP) Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA) Secretariat of the Environment and Natural Resources (SEMARNAT) Secretariat of	Oversees the compliance of several administrative procedures. Refers to different laws, acts, and norms other than those directly created from the law.	https://bit.ly/3CLFJ87

					Health (SSA) Intersecretarial Commission on Biosecurity of Genetically Modified Organisms (CIBIOGEM) National Council of Science and Technology (CONACyT)		
Mexican Official Standard: List of the most commonly transported hazardous substances and materials.	Mexico	High-risk biological materials	Transportation within the national territory	It is limited to the transportation of highly dangerous biological material.	Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA) Secretariat of Transport	Defines which are the substances that are considered high risk and reference other regulations that indicate the specifics of the procedures that should be	https://conacyt.mx/cibiogem/images/cibiogem/normatividad/vigente/NORMAS/NOM-00

					and communication	followed	2-SCT-2011.pdf
Rule of USDA´s Movement of Certain Genetically Modified Organisms	United States	Genetically Modified Organisms	National and International transportation	GE organisms that pose a plant pest risk would fall within the scope of the proposed regulations and require permits for movement.	Animal and Plant Health Inspection Service United States Department of Agriculture Environmental Protection Agency Food and Drug Administration	This rule evaluates GE organisms for plant pest risk with greater precision than the current approach allows.	https://www.regulations.gov/document/APHIS-2018-0034-0037

Table 1. The present work will analyze a brief description of the laws related to transporting biological materials or genetically modified organisms. In the case of Mexican legislation, acronyms correspond to those in Spanish.

ANALYSIS

History and the policies process

The process to generate a new law or regulation in Mexico consists of several stages. First, a law initiative is made, and those who can do this are the President, the representatives, and senators of the Congress of the Union.

Then, this is taken to the Chamber of Representatives or the Senate, and a procedure is dictated. The commission then analyzes the initiative and prepares an opinion that is delivered to the plenary (representatives or senators).

The bill is sent to the revising Chamber, or its publication is ordered. Subsequently, the act (the document containing the bill or reform) is received by the Plenary of the reviewing Chamber, which issues a ruling. The bill is referred to one or more legislative commissions, which analyze it and prepare an opinion for discussion and voting within the commission itself. The plenary discusses and votes on the opinion. Afterward, the plenary discusses and votes on the opinion.

The decree approved by both Chambers is then received by the Federal Executive (the President) for publication in the Official Gazette of the Federation; he may or may not make observations, and if the bill is not returned after 30 days, it is considered approved. Finally, the approved bill is published in the Official Gazette of the Federation.

Now that we have this in mind, a brief review of the origins of each of the Mexican legal documents analyzed in this work is presented in the following paragraphs.

Law on Biosecurity of Genetically Modified Organisms (LBOGM)

The adoption of policies on biosafety and biotechnology appeared slowly in Mexico, but attention on this area was markedly increased with the signing and adoption of the Convention on Biological Diversity in 1992-93. After this, the Cartagena Protocol was signed and incorporated nationally in 2003, which eventually led to the creation of the LBOGM (Álvarez, 2009).

This law was first promulgated in 2005 and caused the amendment of other laws (Álvarez, 2009). The law was recently updated in 2020, yet it stills delimits the governance regarding any activity regarding the processing, transportation, and/or commercialization of genetically modified organisms. Despite not counting with a transportation-centered section, the law references an administrative procedure to be followed when desiring to import a genetically modified organism. The overall chronological procedure governing this process can be found in Table 2.

Name of the procedure	Time of response	Cost	Government department to comply	Link
Notice of Contained Use of Genetically Modified Organisms*	1 week	$0 MXN ($0 USD)	SEMARNAT	https://bit.ly/2XZsCl2
Application for an experimental release permit to the environment, including the import for that activity, of one or more GMOs	24 weeks	$61,393.71 MXN (~$3061 USD)	SENASICA	https://bit.ly/39GdFqa
Permission for experimental release into the environment, including import for that activity, of genetically modified organisms	24 weeks	$30,357.35 MXN (~$1513 USD)	SEMARNAT	https://bit.ly/39CzsyW
Application for a permit for release into the environment in a pilot program including the import of GMOs for that activity	12 weeks	$61,393.72 MXN (~$3061 USD)	SENASICA	https://bit.ly/3lU36pg
Permission for release into the environment in a pilot program, including the import of genetically modified organisms for that activity	12 weeks	$30,357.35 MXN (~$1513 USD)	SEMARNAT	https://bit.ly/3kH0ETF
Application for authorization to market and import GMOs	36 weeks	$234,968 MXN (~$11714 USD)	COFEPRIS	https://bit.ly/2Zmyy7V
Application for a permit	16 weeks	$61,393.72	SENASICA	https://bit.ly/3E

for commercial release into the environment, including the import for that activity of GMOs		MXN (~$3061 USD)		Syxc5
Permission for commercial release into the environment, including import for that activity, of genetically modified organisms	16 weeks	$30,357.35 MXN (~$1513 USD)	SEMARNAT	https://bit.ly/3m1oeKo

Table 2. Chronological order of the government regarding the importation and commercialization of GMOs under the LBOGM. As it can be observed, over $25,000 USD can be spent solely on the fees required to be covered in each step. *Independent permission request for confined use of GMOs.

NOM-002-SCT/2011: Mexican Official Standard: List of the most commonly transported hazardous substances and materials.

The Ministry of Communications and Transportation (SCT) published on the Official Gazette of the Federation (DOF) the Draft Mexican Official Standard NOM-002-SCT/2011, where it enlists the substances and materials that may pose a danger to transport.

The main objective of this law is that for safety and efficiency purposes, it is necessary to establish for the different modes of transport, uniformity in the Official Designation for the Transport of hazardous substances and materials, their corresponding UN number, the risk class, the type of container and packaging, the special provisions that must be applied, as well as the reference to the appropriate container and packaging instruction for each hazardous substance or material in question.

Rule of USDA's Movement of Certain Genetically Engineered Organisms

On the other hand, it can be found in the rule of USDA's Movement of Certain Genetically Engineered (GE) Organisms, which amends regulations regarding the movement (importation, interstate movement, and environmental release) of certain genetically engineered organisms in response to advances in genetic engineering.

According to USDA, this final rule, which marks the first comprehensive revision of the regulations since they were established in 1987, provides a clear, predictable,

and efficient regulatory pathway for innovators, facilitating the development of genetically engineered organisms that are unlikely to pose plant pest risks.

This rule focuses on the properties of the GE organism itself rather than on the method used to produce it. This rule enables us to evaluate GE organisms for plant pest risk with greater precision than the current approach allows. GE organisms that pose a plant pest risk would fall within the scope of the proposed regulations and require permits for movement. Other GE non-plant organisms that do not pose a plant pest risk would not fall under the scope of the regulations and therefore would not require permits for movement.

Applicability of the Regulations

Modified GE plants would not be regulated or subject to a regulatory status review if:

- Genetic modification is solely a deletion of any size; or
- Genetic modification is a single base pair substitution; or
- The genetic modification is solely introducing nucleic acid sequences from within the plant's natural gene pool or from editing nucleic acid sequences in a plant to correspond to a sequence known to occur in that plant's natural gene pool; or
- The plant is an offspring of a GE plant and does not retain the genetic modification in the GE plant parent.

The following categories of GE organisms would be allowed to move only under permit:

- The GE organism is a plant that has a plant-trait-MOA combination that has not been subjected to a regulatory status review in accordance with § 340.4; or
- The GE organism meets the definition of plant pest in § 340.3; or
- The GE organism is not a plant but has received DNA from a plant pest and the DNA from the donor organism either is capable of producing an infectious agent that causes plant disease or encodes a compound that is capable of causing plant disease; or
- The GE organism is a microorganism used to control plant pests or an invertebrate predator or parasite (parasitoid) used to control invertebrate plant pests and could pose a plant pest risk.

Requisites

This rule requires that a responsible person and his or her agent(s) would have to establish and keep the following records and reports:

- All records and reports required as a condition of a permit;
- Addresses and any other information, e.g., GPS coordinates and maps, needed to identify all locations where the organism under permit was stored or used, including all contained facilities and environmental release locations;
- A copy of the APHIS (Animal and Plant Health Inspection Service) permit authorizing the permitted activity; and
- Legible copies of contracts between the responsible person and all agents that conduct activities subject to the regulations for the responsible person and copies and documents relating to agreements made without a written contract.

DISCUSSION

The LBOGM emerged as a response to the already established Cartagena Protocol. Due to this, several ambiguities within the law and in the documents and regulations derived from it can be observed. In the first place, ambiguities concerning the type of GMO towards whom the law is directed. This is reflected in the fact that the law in fact establishes a GMO as "any organism that has acquired a novel genetic combination due to modern biotechnology techniques" (LBOGM, 2020), but there is a lack of clarity in the language used in the other rules and standards emerging from the LBOGM since they seem to be focused towards genetically modified crops or plants for final consumption. Therefore, the law fails to offer a specific and clear landscape for products employing GMOs intended to be applied within industrial or other types of contexts other than in the food industry.

Besides, the law also oversees the transport of GMOs, yet it still lacks clear requirements on this matter, either directly with GMOs or products derived from GMOs, either within national territory or across international borders. A bylaw of the LBOGM barely mentions that imported GMOs must comply with the proper certifications and permissions from the country of origin, but the law refers to other legal rules, such as de Mexican Official Standard previously mentioned, in order to mention the formalities needed to be fulfilled for a correct transport.

The most important part that is to be taken into consideration of the Mexican Official standard for the transport of possibly hazardous materials is that, with regards to the transit of biological materials, this is the closest to a transit regulation that it is available in the country. The LBOGM covers the do and don'ts of the research, development, and commercialization of GM products, with an important focus on the agricultural field however, it does not cover the transit of organisms or offers any protocol to maintain a standard with these substances. On

the other extreme the Mexican Official standard only offers guidance for biological products that are extremely risky, at the same level as firearms and chemical reactants. There is a huge legal void in the transit of GMOs that are not intended for agricultural processes and other related substances, such as lyophilized DNA.

RESPONSE

Proposal

Mexican regulations towards the transit of biotechnological products require an update. As we previously discussed, they don't have the scope necessary to offer reliable methods that are both effective to protect the environment and society from danger and promote new research and the development of new technologies. The reason we added the USDA's Movement of Certain Genetically Engineered Organisms to this document is that even if it is not perfect, it is an excellent example of how will a more open policy would look like. We can take the best from it to apply it in our country.

Our proposal is focused on filling up the legal vacuum that the current Mexican regulations have by adding into the LBOGM the USDA's evaluation of the GMO and other biological materials by taking into consideration the following:

- To make clear distinctions between the type of GMO / biological material, based on its properties and composition, establish a registry of who, when, and why transport biological material to prevent misuse.
- Develop a separate regulation that deals specifically with the transit of biological materials that do not directly represent a high risk, both within the national territory and in import and export, to fill the gap of biological materials that still need to be monitored but are not considered high risk in the transit regulation.

We expect that by adding specific procedures for the transport of GMO and genetic material, scientists will find fewer legal struggles to develop their projects, while the government maintains the appropriate security measures.

REFERENCES

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